

BEFORE THE IOWA BOARD OF PHARMACY

| | |
|---|--|
| RE: Nonresident Pharmacy License of EMPOWER PHARMACY License No. 4263 Respondent | CASE NO. 2018-123 NOTICE OF HEARING AND STATEMENT OF CHARGES |
|---|--|

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Empower Pharmacy ("Respondent"), 5980 W Sam Houston Pkwy N, Ste 300, Houston TX 77041, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.6 and 35.7. Respondent's Iowa nonresident pharmacy license number 4263 is currently active through December 31, 2019.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on September 10, 2019, before the Board. The hearing shall begin at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines IA 50309.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to Amanda.Woltz@iowa.gov, or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 50309.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

Prosecution. The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to Laura.Steffensmeier@ag.iowa.gov, or by mail/delivery to the following address:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines IA 50319

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 155A, and 272C (2018).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 155A, and 272C, and 657 IAC chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

C. STATEMENT OF CHARGES

COUNT I

COMPOUNDING ESSENTIALLY COPIES OF APPROVED DRUGS

Respondent is charged with compounding essentially copies of approved drugs in violation of the requirements of 657 IAC 20.12, and may be disciplined pursuant to Iowa Code section 155A.13A(5)(d) and 657 IAC 19.11(5) and 36.6(21).

D. FACTUAL CIRCUMSTANCES

1. Respondent's nonresident pharmacy license number 4263 is currently active through December 31, 2019.

2. On June 13, 2018, the Oklahoma State Board of Pharmacy approved an Agreed Order in which Respondent agreed to pay a fine to resolve allegations of compounding commercially available or essentially copies of commercially available FDA-approved drug products.

3. In 2017 and 2018, Respondent shipped human chorionic gonadotropin (HCG) in the following formulations to Iowa patients: 5,000 IU; 6,000 IU; 11,000 IU; and 12,000 IU.

4. FDA-approved HCG is commercially available in 5,000 IU and 10,000 IU formulations.

5. Based on the factors described in 657 IAC 20.12(1), Respondent's HCG preparations are essentially copies of the commercially available products.

6. Respondent's prescription documentation did not clearly indicate the relevant change and the significant clinical difference produced for the patient as required by 657 IAC 20.12(2).

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

F. FINDING OF PROBABLE CAUSE

On July 9, 2019, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copies to:

Michael M. Sellers
400 Locust St, Ste 170
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St

Des Moines, IA 50319
ATTORNEY FOR THE STATE

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).